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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,290	04/12/2000	Tatsuya Sasakawa	0018-1098-0	6669

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/548,290	SASAKAWA ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/11/03 has been entered. As requested, the after-final amendment received on 11/13/03 has also been entered. Claim 31 has been canceled. Claims 29-30, and 32-37 are currently pending and under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in previous office actions.

Claim Rejections - 35 USC § 103

The rejection of claims 29-36 under 35 U.S.C. 103(a) as being unpatentable over Morita et al. in view of Yasue et al. is withdrawn in view of the applicant's amendment or cancellation of the claims. Please note however, that pending claims 29-30, and 31-36 are subject to new grounds of rejection under 35 U.S.C. 103(a), see below.

The rejection of claim 37 under 35 U.S.C. 103(a) as being unpatentable over Morita et al. in view of Yasue et al. and Hiroi et al. is withdrawn in view of applicant amendment to the claim. Please note however, that claim 37 is newly rejected under 35 U.S.C. 103(a) below.

Applicant's amendments to the claims have necessitated the following new grounds of rejection.

Claims 29-30, and 32-36 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Morita et al. (1999), J. Derm. Science., Vol. 19, 37-43 in view of Yasue et al. (1997) Cell. Immunol., Vol. 181, 30-37, and S.C. Gad (1994) Toxicology, Vol. 93 (1), 33-46. The applicant claims an animal model for atopic dermatitis which an NC/nga mouse which has been sensitized with a mite extract on the ear under specific pathogen free environment such that the animal displays symptoms of atopic dermatitis caused by the mite extract.

Morita et al. teaches NC mice, an inbred strain of fancy mice established in 1955, which have been bred under specific pathogen free conditions and renamed NC/kuj. It is noted that NC mice bred under regular conditions are typically referred to as NC/Nga mice and are further known to spontaneously develop allergic symptoms which resemble atopic dermatitis (Morita et al., page 38, column 1). Morita et al. further teaches the exposure of specific pathogen free NC mice to fur mites for two weeks, wherein the fur mite exposure results in skin lesions resembling those associated with atopic dermatitis and anti-mite IgE production (Morita et al., page 39, and page 41). Morita concludes that specific pathogen free NC mice exposed to mite antigen represent a mouse model for atopic dermatitis (Morita et al., page 42, column 2).

While Morita et al. teaches how to make a mite extract, see page 38, column 2, paragraph 4, Morita et al. does not specifically teach administering a mite extract rather than live mites to specific pathogen free NC mice in order to produce a mouse model for atopic dermatitis. Yasue et al. supplements Morita by teaching that the administration of mite extract to generate allergic responses in mice is a standard procedure (Yasue et al., page 30, column 2, and page 32). It is further noted that the skilled artisan would be motivated to use a mite extract over live mites in order to standardize the amount of antigen to which each mouse is exposed, thereby ensuring a homogenous population of exposed mice. Thus, in order to produce a more homogeneous population of mite sensitized mice for use as an animal model of atopic dermatitis, it would have been *prima facie* obvious to the skilled artisan to substitute mite extract sensitization as taught by Yasue et al. for the live mite exposure taught by Morita et al. in the method of producing a murine model of atopic dermatitis taught by Morita et al. Further, based on the successful use of mite extracts to generate allergic responses in mice as taught by Yasue et al., the skilled artisan would have had a reasonable expectation of success in generating a mouse model of atopic dermatitis by exposing specific pathogen free NC mice to a mite extract.

Neither Morita et al. nor Yasue et al. specifically teach exposing the ears of NC mice to live mites or to mite extract, although it is noted that exposure of NC mice to live mites may result in live mites on the ears. However, S. C. Gad supplements Morita et al. and Yasue et al. by teaching that the application of an allergen or irritant to mouse ears results in an objective and quantifiable response, measured as ear swelling (Gad, page 34, 36, and 40). Gad states that evaluation of allergic responses when animals have been sensitized at sites that do not include the ears is more subjective and qualitative and thus less desirable than ear sensitization (Gad,

page 40). Thus, Gad provides motivation for sensitizing a mouse with an allergen on the ear. Therefore, in view of the teachings provided by Gad that ear sensitization with allergen is more objective and quantifiable than other sites of allergen sensitization, it would have been *prima facie* obvious to the skilled artisan at the time of filing to apply the mite extract taught by Yasue et al. on the ears of the NC mice in the mouse model of atopic dermatitis taught by Morita et al. Further, based on the successful use of mite extracts to generate allergic responses in mice as taught by Yasue et al., and the teachings of Gad that the ears are sensitive to allergic reactions, the skilled artisan would have had a reasonable expectation of success in generating a mouse model of atopic dermatitis by exposing specific pathogen free NC mice to a mite extract on the ears.

Claim 37 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Morita et al. (1999), J. Derm. Science., Vol. 19, 37-43 in view of Yasue et al. (1997) Cell. Immunol., Vol. 181, 30-37, and S.C. Gad (1994) Toxicology, Vol. 93 (1), 33-46 as applied to claims 29-30, and 32-36 above, and further in view of Hiroi et al. (1998) Jpn. J. Pharmacol., Vol. 76, 175-183. The applicant claims methods of screening for an agent effective against atopic dermatitis or useful for preventing atopic dermatitis comprising applying at least one agent to an NC/nga mouse which has been sensitized with a mite extract on the ear under specific pathogen free environment such that the animal displays symptoms of atopic dermatitis caused by the mite extract and determining whether the agent reduces or prevents allergy symptoms.

As discussed in detail in the preceding rejection, Morita et al. in view of Yasue et al. and Gad provides the motivation and teachings for a mouse model of atopic dermatitis comprising an NC/nga mouse sensitized under specific pathogen free conditions with mite extract on the ear.

Morita et al., Yasue et al., and Gad do not specifically teach using these mice to test for therapeutic compounds effective against atopic dermatitis. However, it is noted that Morita et al. does teach that the administration of ivermectin to NC mice treated with live mites reduces anti-mite IgE levels and skin lesions (Morita et al., pages 41-42). This demonstrates that the mice are suitable for testing potential therapeutic agents. Hiroi et al. further supplements Morita et al. by providing motivation for testing potential therapeutic agents in mouse models of atopic dermatitis. Hiroi teaches that the standard model for spontaneous atopic dermatitis, NC mice raised under conventional and not specific pathogen free conditions, can be used to screen for therapeutic agents. Specifically, Hiroi teaches that FK506 ointment, not betamethasone valerate ointment, was determined to be effective in suppressing and inhibiting symptoms of atopic dermatitis when applied to NC mice both before and after the development of dermatological symptoms (Hiroi et al., page 176 and Figure 1, 2, and 3). Thus, in view of the motivation provided by Hiroi et al. for using murine models of atopic dermatitis to determine the effectiveness of agents in preventing or inhibiting atopic dermatitis, it would have been *prima facie* obvious to use the screen agents for effectiveness against atopic dermatitis using the mouse model of atopic dermatitis as taught by Morita et al. in view of Yasue et al. and Gad. Further, based on the demonstration by Morita et al. that ivermectin is useful for treating atopic dermatitis like symptoms in the mouse model of atopic dermatitis developed by Morita et al., the skilled artisan would have had a reasonable expectation of success in testing agents for effectiveness

against atopic dermatitis using NC mice sensitized on the ear with mite extract as taught by Morita et a. in view of Yasue et al. and Gad.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER